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Scynexis issues a voluntary nationwide recall of Brexafemme (ibrexafungerp tablets) due to potential for cross contamination with a non-antibacterial ß-lactam drug substance

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About this recall:

Scynexis is conducting a voluntary nationwide recall of two lots of Brexafemme (ibrexafungerp tablets) to the consumer level in the U.S. market due to potential cross contamination with a non-antibacterial ß-lactam drug substance in the ibrexafungerp citrate used to manufacture the Brexafemme tablets. During a review of manufacturing equipment and cleaning activities at a supplier, Scynexis was made aware of potential cross-contamination risk with a non-antibacterial beta-lactam drug substance. This press release provides additional details on the voluntary product recall recently disclosed by Scynexis.

The potential cross contamination with a non-antibacterial beta-lactam drug substance could lead to hypersensitivity reactions such as swelling, rash, urticaria and anaphylaxis, a potentially life-threatening adverse reaction. To date, Scynexis has not received any reports of adverse events established to be due to the possible beta-lactam cross contamination.

Brexafemme is an antifungal product indicated for the treatment of vulvovaginal candidiasis (VVC) and the reduction of the incidence of recurrent vulvovaginal candidiasis (RVVC). Brexafemme is dispensed in a carton and packaged in blister packs with four 150-mg tablets (NDC 75788-115-04). Brexafemme tablet for oral administration is a purple, oval, biconvex-shaped, film-coated tablet debossed with 150 on one side and SCY on the other side. The affected Brexafemme lots include the following lots and expiration dates: LF21000008 (expiration date 11/2023) and LF22000051 (expiration date 11/2025). The recalled lots were distributed nationwide to wholesalers across the United States, beginning in December 2022.

What this means to you:

Consumers with questions regarding this recall can contact Sedgwick at **877.551.7154**, Monday–Friday, 8 a.m.–5 p.m. Eastern Time (ET).

Consumers should contact their health care provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.